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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,674	03/09/2001	Roberto A. Macina	DEX-0142	9969

7590 10/14/2003

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,674

Applicant(s)

MACINA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 7, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 16.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claim 1 is pending.
Claims 2-5 have been cancelled.
Claim 1 has been amended.
Claim 1 is examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. Applicants note at section I of the Remarks filed August 7, 2003
“...that...references [AD, AE and AS] are not relevant to the novelty and/or obviousness of the claimed subject matter and therefore need not be considered by the Examiner...”.
Therefore, these references will not be reviewed.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 2-5 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence of gastrointestinal cancer in a patient comprising determining levels of a polynucleotide comprising SEQ ID NO: 3 or a polynucleotide encoding a polypeptide comprising SEQ

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ID NO: 4 in cells, tissue or bodily fluids in a patient and comparing the determined levels of a polynucleotide comprising SEQ ID NO: 3 or a polynucleotide encoding a polypeptide comprising SEQ ID NO: 4 in cells, tissue or bodily fluids from a normal human control, wherein a change in determined levels of a polynucleotide comprising SEQ ID NO: 3 or a polynucleotide encoding a polypeptide comprising SEQ ID NO: 4 in said patient versus normal human control is associated with presence of gastrointestinal cancer, does not reasonably provide enablement for methods of diagnosing metastases, staging and monitoring changes in gastrointestinal cancer is withdrawn in view of the cancellation of the claims.

5. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the claim amendment. Claims 2-5 have been cancelled.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication number 2003/0109690 A1 (June 12, 2003). US Patent

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Application Publication number 2003/0109690 teaches sequence 4637, which is the same as Applicants' polypeptide sequence, SEQ ID NO: 4. Moreover, the patent application publication teaches a diagnostic method involving measuring the expression level of polynucleotides in cells or body fluid from an individual and comparing the measured gene expression level, whereby an increase or decrease in the gene expression level compared to the standard is indicative of a disorder, see page 66, section 0341. "[M]easuring the expression level of polynucleotides of the invention' is intended...measuring or estimating the level of polypeptide of the invention or the level of the mRNA encoding the polypeptide of the invention in a first biological sample...(e.g., by determining or estimating absolute protein level or mRNA level) or relatively (e.g., by comparing to the polypeptide level or mRNA level in a second biological sample)", page 66, sections 0344 and 0345. "[T]he polypeptide level or mRNA level in the first biological sample is measured...and compared to a standard polypeptide level or mRNA level, the standard being taken from a second biological sample obtained from an individual not having the related disorder...". The polynucleotides and the polypeptides of the invention listed in the patent application publication may be used to diagnose gastrointestinal disorders, see page 80, sections 0470 and 0471.

The patent application does not teach the explicit use of sequence 4637, which is 100% identical to Applicants' SEQ ID NO: 4. However, it would have been *prima facie* obvious at the time of the claimed invention to implement the teachings of the patent in order to detect the presence of gastrointestinal cancer in a patient. One of ordinary skill


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in the art would have been motivated by teachings of the patent application that performing the taught method with the 100% sequence identical polypeptide, sequence 4637 would yield a result indicative of the presence or absence of gastrointestinal cancer and arrive at "[a] more definitive diagnosis ...[in order to] allow health professionals to employ preventative measures or aggressive treatment earlier thereby preventing the development of further progression of the cancer", see bridging paragraph of pages 63 and 64.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
10 October 2003